

5/9/2014

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

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**MAY 09 2014**

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Ms. Sydney Jarrett  
Syngenta Seeds, Inc. – Field Crops – NAFTA  
P.O. Box 12257  
Research Triangle Park, NC 27709-2257

Subject: Bt11 Insect-Resistant Corn  
EPA Reg. No. 67979-1  
Amendment dated January 6, 2014 to modify reporting requirements and subsequent revisions;  
Amendment dated January 24, 2013 to allow non-refuge compliant growers an option of planting an integrated refuge corn product and subsequent revisions;  
Notification dated May 7, 2013 and subsequent revisions.

Dear Ms. Jarrett:

The amendment and notification referred to above, submitted in connection with registration under FIFRA Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable subject to the following terms and conditions:

- 1] As stated in the amendment approval letter dated 9/29/2010, the subject registration will automatically expire on midnight September 30, 2015.
- 2] Submit/cite all data required for registration of your product under FIFRA section 3(c)(2)(B) when EPA requires registrants of similar products to submit such data.
- 3] The subject registration will be limited to Cry1Ab [*Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (OECD Unique Identifier: SYN-BT011-1) for use in field corn.
- 3] This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.
- 4] You must do the following Insect Resistance Management Program:

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**Insect Resistance Management:**

The required IRM program for *Bt* corn must have the following elements:

- 1] Requirements relating to creation of a non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuge in conjunction with the planting of any acreage of *Bt* corn;
- 2] Requirements for Syngenta Seeds, Inc. (Syngenta) to prepare and require *Bt* corn users to sign "grower agreements" that impose binding contractual obligations on the grower to comply with the refuge requirements;
- 3] Requirements regarding programs to educate growers about IRM requirements;
- 4] Requirements regarding programs to evaluate and promote growers' compliance with IRM requirements;
- 5] Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry IAb protein in the target insects;
- 6] Requirements regarding a "remedial action plan" that contains measures Syngenta would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA;
- 7] Requirements for Syngenta to maintain, and provide the Agency upon request, the number of units sold by state and county, IRM grower agreement results, and substantive changes to educational programs. Syngenta is required to submit reports within three months of the Agency's request.

**a. Refuge Requirements**

These refuge requirements do not apply to seed propagation of inbred and hybrid corn seed corn up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance are provided by Syngenta to help these growers meet the refuge requirements across their farming operations.

**1] Corn-Belt Refuge Requirements**

Field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.

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- External refuges must be planted within 1/2 mile.
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide.
- Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB) and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

2] Cotton-Growing Area Refuge Requirements for *Bt* Corn

For *Bt* field corn grown in cotton-growing areas, grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers in these areas must plant a structured refuge of at least 50% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within 1/2 mile.
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide.
- Insecticide treatments for control of ECB, CEW, Southwestern corn borer (SWCB), and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.
- Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

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b. Grower Agreements

- 1] Persons purchasing the *Bt* corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3] Syngenta must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated-protectants, which is reasonably likely to assure that persons purchasing Bt 11 Insect Resistant Corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4] Syngenta must continue to use its current grower agreement for Bt11 Insect Resistant Corn. If Syngenta wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Syngenta must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this amended registration.
- 5] Syngenta must continue to integrate this amended registration into the current system used for its other *Bt* corn plant-incorporated-protectants, which is reasonably likely to assure that persons purchasing Bt 11 Insect Resistant Corn sign grower agreement(s).
- 6] Syngenta shall maintain records of all *Bt* corn grower agreements for a period of three years from December 31 of the year in which the agreement was signed.
- 7] Syngenta shall make available to the Agency upon request records of the number of units of Bt 11 Insect Resistant Corn seed sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements for the previous growing season. Syngenta is required to submit reports within three months of the Agency's request.
- 8] Syngenta must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c. IRM Education and IRM Compliance Monitoring Programs

- 1] Syngenta must continue to implement and enhance (as set forth in paragraph 16 of this section) a comprehensive, ongoing IRM education program designed to convey to Bt11 Insect Resistant Corn users the importance of complying with the IRM program. The program shall include information encouraging Bt11 Insect Resistant Corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt11 Insect Resistant Corn fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Bt11 Insect Resistant Corn user separate from the grower technical guide.

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The communication shall inform the user of the current IRM requirements. Syngenta shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.

2] Annually, Syngenta shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3] Upon EPA request, Syngenta shall provide copies of grower education materials and information on grower education activities, including any substantive changes to these materials and activities either individually or as part of the industry working group ABSTC. Syngenta is required to submit reports within three months of the Agency's request.

4] Syngenta must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Bt11 Insect Resistant Corn are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Syngenta corn PIP products. Syngenta shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and continue to integrate this amended registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated protectants. Other required features of the program are described in paragraphs 5-21.

5] Syngenta must maintain and publicize a "phased compliance approach," i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers after the first year of noncompliance. While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Syngenta must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two years in a row would be denied access the next year to Syngenta's *Bt* corn products for which the grower is required to plant a separate structured refuge. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Bt11 Insect Resistant Corn.

6] The IRM compliance assurance program shall include an annual survey conducted by an independent third party of a statistically representative sample of growers of *Bt* corn borer protected products who plant the vast majority of all corn in the U.S. and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.

i. A third party is classified as a party other than Syngenta, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

- 8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- 9] Syngenta shall provide a written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31st of each year. Syngenta shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.
- 10] Annually, Syngenta shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Syngenta must confer with the Agency prior to adopting any changes.
- 11] Syngenta shall conduct an annual on-farm assessment program. Syngenta shall train its representatives who make on-farm visits with growers of their *Bt* corn borer protected products to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.
- 12] Syngenta shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Syngenta shall take appropriate action, consistent with its "phased compliance approach."
- 13] If a grower, who purchases *Bt* corn for planting, was specifically identified as not being in compliance during the previous year, Syngenta shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.
- 14] Syngenta shall annually provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one month of submitting this report to EPA, Syngenta shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the noncompliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. Syngenta may elect to coordinate information with other registrants and report collectively the results of their compliance assurance programs.
- 15] Syngenta and the seed corn dealers for Syngenta must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.
- 16] Syngenta will continue to implement and enhance the refuge education program throughout the seed delivery channel:
  - i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge;

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ii. Include the refuge size requirement on all *Bt* corn seed bags or bag tags. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics.

17] Syngenta will continue to focus the majority of on-farm assessments on regions with the greatest risks for resistance:

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where the product is used.

18] Syngenta will continue to use its available *Bt* sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the *Bt* corn product but may have purchased little or no refuge seed from Syngenta, licensee, or affiliated company.

19] Syngenta will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

i. The third-party assessors will conduct all first-time on-farm assessments as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment.

20] Syngenta will annually refine the on-farm assessment program for the *Bt* corn product to reflect the adoption rate and level of refuge compliance for the product.

21] Syngenta will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

- i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of 2 years by Syngenta, a seed supplier, or a third-party assessor, after completing the assessment process.
- ii. Syngenta will conduct follow-up checks on growers found to be significantly out of compliance within 3 years after they are found to be back in compliance.
- iii. A grower found with a second incident of significant non-compliance with refuge requirements for Bt11 Insect Resistant Field Corn within a 5-year period will be denied access the next year to Syngenta's *Bt* corn products for which the grower is required to plant a separate structured refuge.

d. Insect Resistance Monitoring and Remedial Action Plan

The Agency is imposing the following conditions for the Cry1Ab toxin expressed in this product:

Syngenta will continue to monitor for resistance to its lepidopteran-resistant *Bt* com. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than

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expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

### (1) Focused Population Sampling

Syngenta shall annually sample and bioassay populations of the key target pests *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to lepidopteran resistant *Bt* corn and/or changes in resistance allele frequency in response to the use of *Bt* corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of lepidopteran-resistant *Bt* com. The Agency shall be consulted prior to the implementation of such modifications.

Syngenta will report to the Agency before August 31 each year the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the *Bt* protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to *Bt* corn hybrids under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.
3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:



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- determining the nature of the resistance (*i.e.*, recessive or dominant, and the level of functional dominance);
- estimating the resistance-allele frequency in the original population;
- determining whether the resistance-allele frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
- determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Syngenta will consult with the Agency to develop and implement a case-specific resistance management action plan.

**(2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:**

Syngenta will continue to follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Syngenta will instruct its customers to contact them if such incidents occur. Syngenta will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), Syngenta will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

*Suspected resistance*

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to *Bt* corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, Syngenta will instruct growers to do the following:

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- Use alternative control measures in the *Bt* corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy *Bt* corn crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, Syngenta will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

*Confirmed resistance*

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is > 30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of  $\geq 0.1$  in the sampled population.
- In standardized laboratory bioassays, the LC50 exceeds the upper limit of the 95% confidence interval of the LC50 for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

**(3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field**

When field resistance is *confirmed* (as defined above), the following steps will be taken by Syngenta:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;

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- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;
- Syngenta will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Syngenta will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g. growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year for the duration of the conditional registration.

e. Annual Reports

- 1] Compliance Assurance Plan: Compliance Assurance Program activities, including IRM Grower Survey results and on-farm assessment results, for the prior year and plans for the compliance assurance program for the current year on or before January 31<sup>st</sup> each year beginning in 2014;
- 2] Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31<sup>st</sup> each year.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of this product constitutes acceptance of these conditions.

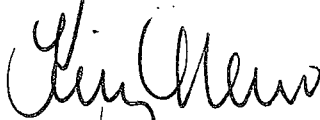
A stamped copy of the label is enclosed for your records.

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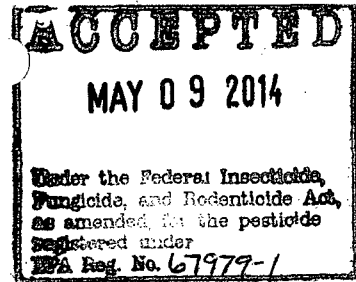
The basic CSF dated May 5, 2014, is acceptable and supersedes all previous basic CSFs. A copy has been placed in the file jacket for this registration.

Sincerely,



Kimberly Nesci, Chief  
Microbial Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511P)

Enclosure: Stamped Label



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**Plant-incorporated Protectant Label**

**Bt11 Insect-Resistant Corn**

Alternate brand names: *Agrisure*<sup>®</sup> CB/LL Corn  
*Agrisure*<sup>®</sup> GT/CB/LL Corn  
Bt11 Corn  
Bt11 Field Corn  
*Agrisure*<sup>®</sup> 3010 Corn  
*Agrisure* Artesian<sup>™</sup> 3010A Corn

OECD Unique Identifier: SYN-BTØ11-1

This product is effective in limiting corn leaf, stalk, and ear damage caused by corn borers and certain other lepidopteran pests.

**Active Ingredient:**

*Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (SYN-BTØ11-1) ..... 0.00014 - 0.0028%\*

**Inert Ingredient:**

Phosphinothricin acetyltransferase protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (SYN-BTØ11-1)..... < 0.000004 – 0.00002%\*

\*Percentage in whole plants on a dry-weight basis

**Keep Out of the Reach of Children  
CAUTION**

EPA Reg. No. 67979-1  
EPA Est. No. 67979-IA-002

Syngenta Seeds, Inc. – Field Crops - NAFTA  
P.O. Box 12257  
3054 East Cornwallis Road  
Research Triangle Park, NC 27709

®, <sup>™</sup> Trademarks of a Syngenta Group company

**Directions for Use**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

The subject registration will automatically expire September 30, 2015.

This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

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All commercial seed corn seed that contains Bt11 Insect-Resistant Corn that is sold by Syngenta Seeds or its distributors must be accompanied by informational material (e.g. bag tag) indicating the EPA registration number and the active ingredients, and stipulating that growers read the product Insect Resistance Management (IRM) Stewardship Guide (or equivalent guidance) prior to planting the seed. The refuge size and requirement must be displayed on the seed bag or bag tag in both text and graphic format as shown below.

**Important grower information.  
This hybrid requires you to plant:**



or



**For more information please refer to the Syngenta Stewardship Guide.**

**Insects Controlled or Suppressed**

Corn has been genetically modified to produce a *Bacillus thuringiensis* Cry1Ab delta-endotoxin protein for control or suppression of:

- European corn borer (*Ostrinia nubilalis*)
- Southwestern corn borer (*Diatraea grandiosella*)
- Southern cornstalk borer (*Diatraea crambidoides*)
- Corn earworm (*Helicoverpa zea*)
- Fall armyworm (*Spodoptera frugiperda*)
- Sugarcane borer (*Diatraea saccharalis*)
- Common stalk borer (*Papaipema nebris*)
- Lesser cornstalk borer (*Elasmopalpus lignosellus*)

**Insect Resistance Management**

An IRM Stewardship Guide (or equivalent guidance) must be distributed to all customers using seed containing the plant incorporated-protectant. The IRM Stewardship Guide will include instructions and recommendations regarding product use, insect resistance management, and integrated pest management. The following information regarding refuge requirements for commercial production must be included in the IRM Stewardship Guide for the corn belt and cotton-growing areas.

These IRM requirements do not apply to breeding, research, propagation of inbred seed, or production of hybrid seed corn on up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per plant-incorporated protectant active ingredient per registrant per year.

**Corn Belt (Noncotton-Growing Areas)**

For Bt11 Insect-Resistant Corn grown in the Corn Belt (noncotton-growing areas), growers must adhere to the following refuge requirements:

- Growers must plant a refuge of at least 20% non-Bt corn and/or non-lepidopteran-resistant Bt corn.
- The refuge can be planted as a block, strips within the field, perimeter around the field, adjacent or a separate block planted within ½ mile.
- A neighbor's field does not meet the refuge requirements.
- Strips, blocks, or perimeter refuges must be a minimum of 4 contiguous rows wide.
- Non-Bt foliar insecticide treatments for corn borer control may be applied only if economic thresholds are reached for one or more pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g. Extension service agents, crop consultants).
- The refuge should be planted with a hybrid that is agronomically similar to and managed similarly to the Bt11 Insect-Resistant Corn.

**Cotton-Growing Areas**

For Bt11 Insect-Resistant Corn grown in cotton-growing areas (defined below) growers must adhere to the following refuge requirements.

- Growers must plant a refuge of at least 50% non-Bt corn and/or non-lepidopteran-resistant Bt corn.
- The refuge can be planted as a block, strips within the field, perimeter around the field, adjacent or a separate block planted within ½ mile.
- A neighbor's field does not meet the refuge requirements.
- Strips, blocks, or perimeter refuges must be a minimum of 4 contiguous rows wide.
- Non-Bt foliar insecticide treatments for corn borer control may be applied only if economic thresholds are reached for one or more pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g. Extension service agents, crop consultants).
- The refuge should be planted with a hybrid that is agronomically similar to and managed similarly to the Bt11 Insect-Resistant Corn.

The following table lists those states and counties identified by the Environmental Protection Agency (EPA) as cotton-growing areas.

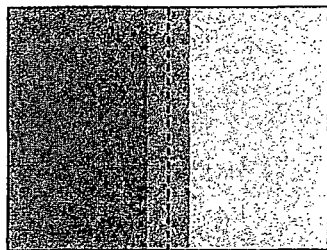
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State	Counties Identified by EPA as Cotton-Growing Areas			
Alabama	All Counties			
Arkansas	All Counties			
Florida	All Counties			
Georgia	All Counties			
Louisiana	All Counties			
Mississippi	All Counties			
Missouri	Dunklin Stoddard	New Madrid	Pemiscot	Scott
North Carolina	All Counties			
Oklahoma	Beckham Greer Kiowa	Caddo Harmon Tillman	Comanche Jackson Washita	Custer Kay
South Carolina	All Counties			
Tennessee	Carroll Fayette Hardin Lincoln Shelby	Chester Franklin Haywood Madison Tipton	Crockett Gibson Lake Obion	Dyer Hardeman Lauderdale Rutherford
Texas	All counties with the exception of the following:			
	Carson Hutchinson Roberts	Dallam Lipscomb Sherman	Hansford Moore	Hartley Ochiltree
Virginia	Dinwiddie Northampton Sussex	Franklin City Southampton	Greensville Suffolk City	Isle of Wight Surrey



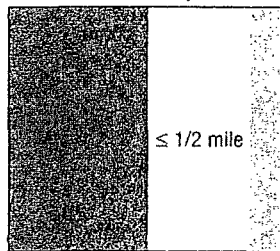
Schematics showing refuge deployment options:

**Adjacent**



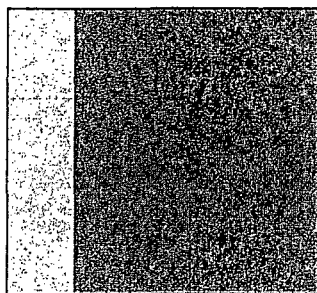
Can be separated by a road, path, ditch, etc., but not by another field.

**1/2 Mile Option**

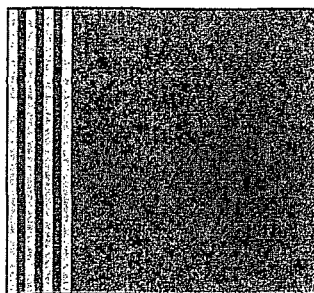


Corn Borer Refuge Option Only

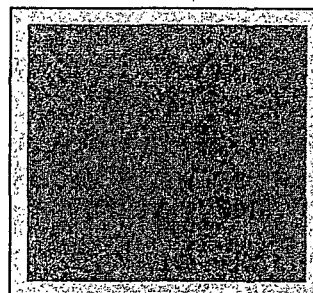
**Within**



Block



Strips (Split Planter)



Perimeter